UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

LIFESCAN SCOTLAND, LTD, Plaintiff, v. SHASTA TECHNOLOGIES, LLC, ET AL., Defendants.	Case No.: 5:11-CV-04494 EJD **ORDER DENYING MOTION FOR JUDGMENT ON THE PLEADINGS AND DENYING MOTION TO STAY** **(Re: Docket Nos. 43 and 44)**

Pending before the court are (1) Defendant Instacare Corp. ("Instacare") and Defendant Pharmatech Solutions, Inc.'s ("Pharmatech") motion for judgment on the pleadings, or, in the alternative, to stay; and (2) Defendant Conductive Technologies, Inc. ("Conductive") and Defendant Shasta Technologies, LLC's ("Shasta") motion to stay. For the reasons discussed below, Instacare and Pharmatech's motion for judgment on the pleadings or, in the alternative, to stay is DENIED. Conductive and Shasta's motion to stay are DENIED.

I. BACKGROUND

A. Pleadings

On September 9, 2011, Plaintiff LifeScan Scotland, Ltd. ("LifeScan") filed its Complaint initiating this action. In the Complaint, LifeScan alleges a declaratory judgment action for

infringement of U.S. Patent No. 5,708,247 (the '247 patent) and of U.S. Patent No. 6,241,862 (the '862 patent). The Complaint alleges the following facts:

LifeScan owns the '247 and the '862 patent and sells strips for blood glucose testing under the name OneTouch Ultra, which are designed for use with the OneTouch Ultra family of glucose monitors. See Compl. ¶¶ 15, 17, 18, 20. The OneTouch Ultra test strips are manufactured by methods within the scope of the '247 or '862 patent claims. Id. ¶ 19.

Defendants manufacture or threaten to manufacture test strips for glucose diagnostics under the name Genstrips ("Genstrips"), which are also designed to work with the OneTouch meters to provide accurate and useable readings. Id. ¶ 23. The process for manufacturing Genstrips is within the scope of one or more claims of the patents-in-suit. Id. ¶ 31.

Shasta has applied to the United States Food and Drug Administration ("FDA") for pre-market approval of Genstrips and has applied to various regulatory bodies around the world seeking to market its Genstrips in those countries. Id. ¶¶ 24-25. Shasta and PharmaTech have entered an agreement regarding the control, management, and distribution of Genstrips, including distribution within the United States. Id. ¶ 26. Shasta, PharmaTech, or InstaCare have entered into an agreement with Conductive regarding the manufacture of Genstrips, including for distribution within the United States. Id. ¶ 27. On May 24, 2011, InstaCare issued sales guidance regarding Genstrips, projecting 2011 sales at $41.8 million and 2012 sales at $206.6 million. Id. ¶ 32. According to InstaCare's website, InstaCare anticipates making over $40 million in Genstrips commercial sales in 2011, either within the Unites States or outside of the United States. Such sales outside the United States do not require FDA approval. Id. ¶ 44. Defendants have taken substantial steps in preparation to make Genstrips or have Genstrips made, including, but not limited to designing the Genstrips, applying for FDA approval of the Genstrips, arranging for distribution of the Genstrips, and stockpiling Genstrips in the United States for distribution upon regulatory approval. Id. ¶ 61

Based on these facts, LifeScan alleges that Shasta, InstaCare, and PharmaTech have actively induced infringement and threaten to actively induce infringement of one or more claims

of the '247 patent by having Genstrips made for distribution within the United States. Id. ¶¶ 63, 71. LifeScan further alleges that LifeScan is under a reasonable apprehension that the Defendants will infringe or actively induce infringement of the '247 patent and the '862 patent. Id. ¶¶ 64, 72.

On October 14, 2011, Instacare and Pharmatech filed their Answer and Shasta and Conductive filed their Answer.

B. Procedural Background

On December 14, 2010, Instacare and Pharmatech filed their motion for judgment on the pleadings or for a stay. See Docket No. 43. On December 16, 2011, Conductive and Shasta filed their motion for a stay. See Docket No. 44. On January 20, 2012, the parties appeared for a case management conference. Following discussion at the case management conference about whether discovery should proceed in light of Defendants having filed the instant motions to stay and motion for judgment on the pleadings, the undersigned ordered that the parties shall not notice depositions until after the court ruling on these motions. See Case Management Order at 2:5-7, Docket No. 71.

On March 21, 2012, the court took the motions to stay and the motion for judgment on the pleadings under submission without oral argument. See Docket No. 86; Civil L.R. 7-1(b). On May 17, 2012, the court granted LifeScan's motion to allow LifeScan to file the Supplemental Declaration of Eugene M. Gelernter in support of LifeScan's opposition to the motions to stay and motion for judgment on the pleadings. See Decl. of Eugene Gelertner Suppl. Pl.'s Opp'n ("Suppl. Gelertner Decl."), Docket No. 92-1; Order Granting Pl.'s Mot. Admin. Relief, Docket No. 95.

II. LEGAL STANDARDS

A. Motion for Judgment on the Pleadings

Federal Rule of Civil Procedure 12(c) provides that "[a]fter the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." A Rule 12(c) motion challenges the legal sufficiency of the opposing party's pleadings. Judgment on the pleadings is appropriate when, even if all material facts in the pleading under attack are true, the moving party is entitled to judgment as a matter of law. Fleming v. Pickard, 581 F. 3d 922, 925 (9th Cir. 2009).

On a motion for judgment on the pleadings, "all material allegations in the complaint are accepted as true and construed in the light most favorable to the non-moving party." Turner v. Cook, 362 F. 3d 1219, 1225 (9th Cir. 2004). "[A]ll reasonable inferences" must be made "in favor of the nonmoving party." Mediran v. International Ass'n of Machinists and Aerospace Workers, No. C09–0538 TEH, 2011 WL 2746601, at *2 (N.D. Cal. July 14, 2011). "When considering a motion for judgment on the pleadings, this court may consider facts that 'are contained in materials of which the court may take judicial notice.'" Heliotrope General, Inc. v. Ford Motor Co., 189 F.3d 971, 981, n.18 (9th Cir. 1999) (citation omitted). A motion for judgment on the pleadings may be granted if, after assessing the complaint and matters for which judicial notice is proper, it appears "beyond doubt that the [non-moving party] cannot prove any facts that would support his claim for relief." Morgan v. County of Yolo, 436 F. Supp. 2d 1152, 1155 (E.D. Cal. 2006).

B. Motion To Dismiss For Lack of Jurisdiction

The court examines a portion of Instacare and Pharmatech's motion brought under Rule 12(c) as raising concerns governed by Rule 12(b)(1) of the Federal Rules of Civil Procedure, which covers motions to dismiss for "lack of subject matter jurisdiction." A motion to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1) may either attack the allegations of the complaint as insufficient to confer subject matter jurisdiction, or attack the existence of subject matter jurisdiction in fact. Safe Air for Everyone v. Meyer 373 F.3d 1035, 1039 (9th Cir. 2004) ("In a facial attack, the challenger asserts that the allegations contained in a complaint are insufficient on their face to invoke federal jurisdiction. By contrast, in a factual attack, the challenger disputes the truth of the allegations that, by themselves, would otherwise invoke federal jurisdiction.").

"In a facial attack, the court must consider whether the complaint, on its face, sufficiently alleges state action, presuming all allegations to be true." Rimac v. Duncan, 319 Fed.Appx. 535, 536 (9th Cir. 2009). If the attack is factual, the plaintiff's allegations are not entitled to a presumption of truthfulness, a court may look beyond the pleadings to resolve factual disputes, and the plaintiff has the burden of proving that jurisdiction exists. Safe Air for Everyone, 373 F.3d at 1039.

C. Declaratory Judgments Act

The Declaratory Judgments Act authorizes the court to "declare the rights and other legal relations of any interested party seeking such declaration" when there is an "actual controversy." 28 U.S.C. § 2201(a).

The requirement for federal court jurisdiction under Article III of the U.S. Constitution and the Declaratory Judgment Act is an "actual controversy." Teva Pharms. USA, Inc. v. Novartis Pharms. Corp., 482 F.3d 1330, 1338 (Fed. Cir. 2007). The "actual controversy" requirement of the Declaratory Judgment Act demands only "that the dispute be definite and concrete, touching the legal relations of parties having adverse legal interests; that it be real and substantial and admit of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 127 (2007) (citations and quotations omitted). "[T]he question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." Id.

Prior to MedImmune, the Federal Circuit had generally required that a declaratory judgment plaintiff seeking declaration of non-infringement demonstrate (1) conduct by the patentee that created a "reasonable apprehension" of suit on the part of the declaratory judgment plaintiff and (2) present activity by the declaratory judgment Plaintiff that could constitute infringement or "meaningful preparation" to conduct potentially infringing activity. See, e.g., Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1571 (Fed. Cir. 1997). When the owner of a patent sought declaratory judgment of infringement, the modified test required that two elements must be present: "(1) the defendant must be engaged in an activity directed toward making, selling, or using subject to an infringement charge under 35 U.S.C. § 271(a) (1982), or be making meaningful preparation for such activity [reality]; and (2) acts of the defendant must indicate a refusal to change the course of its actions in the face of acts by the patentee sufficient to create a reasonable apprehension that a suit will be forthcoming [immediacy]." Lang v. Pacific Marine & Supply Co.

Ltd., 895 F.2d 761, 764 (Fed. Cir. 1990). Although the Supreme Court has rejected the reasonable-apprehension-of-suit test as the sole test for jurisdiction, it is still considered one of many ways that a declaratory judgment plaintiff might satisfy the totality of circumstances test in establishing the existence of a justiciable controversy. Prasco LLC v. Medicis Pharmaceutical Corp., 537 F.3d 1329, 1336 (Fed. Cir. 2008).

Even when an actual controversy exists, the court has substantial discretion to decline jurisdiction, as the "statute provides that a court 'may declare the rights and other legal relations of an interested party.'" Wilton v. Seven Falls Co., 515 U.S. 277, 286 (1995) (quoting 28 U.S.C. § 2201(a)). Such relief is appropriate where the judgment will "serve a useful purpose in clarifying and settling the legal relations in issue, and . . . will terminate and afford relief from the uncertainty, insecurity, and controversy giving rise to the proceeding." Guerra v. Sutton, 783 F.2d 1371, 1376 (9th Cir. 1986) (quoting Bilbrey by Bilbrey v. Brown, 738 F.2d 1462, 1470 (9th Cir. 1984)). "In the declaratory judgment context, the normal principle that federal courts should adjudicate claims within their jurisdiction yields to considerations of practicality and wise judicial administration." Wilton, 515 U.S. at 288.

D. Section 271(e)(1)

The United States Code states that except as otherwise provided in title 35, whoever without authority "makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent . . . infringes the patent." 35 U.S.C. § 271(a).

Section 271(e)(1) creates a limited exception to this provision:

> "It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs or veterinary biological products."

35 .S.C. § 271(e)(1).

III. DISCUSSION

A. Request for Judicial Notice

On January 6, 2012, LifeScan filed a request for judicial notice of the following documents:

1. InstaCare's Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the quarterly period ended June 30, 2011, filed with the United States Securities and Exchange Commission ("S.E.C.") on September 15, 2011 on Form 10-Q/A. Howard Decl. Ex. A.

2. InstaCare Corp.'s Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the quarterly period ended September 30, 2011, filed with the SEC on November 21, 2011 on Form 10-Q. Howard Decl. Ex. B.

3. Defendant InstaCare Corp.'s December 27, 2011 press release: "Decision Diagnostic Corp. Clarifies 10% Stock Dividend, Announces Patent Enforcement Strategy." Howard Decl. Ex. C.

4. Portion of Defendant Pharamtech Solutions, Inc.'s website, http://www.pharmatechdirect.com/. Howard Decl. Ex. D.

5. Letter from LifeScan Scotland's counsel to Magistrate Judge Paul Grewal dated December 2, 2011. Howard Decl. Ex. E.

See Docket No. 49-1.

On January 18, 2012, Instacare and Pharmatech filed an objection to the request for judicial notice. In their objection, Instacare and Pharmatech argue that "the [c]ourt can take judicial notice of the existence of the documents, it should not take judicial notice of the out-of-court statements made" in those documents because the statements are hearsay. Docket No. 60 at 2:14-17 (emphasis in original).

A "court may judicially notice a fact that is not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." FRE 201(b).

The court GRANTS LifeScan's unopposed request for judicial notice. As Instacare and Pharmatech point out, however, "judicial notice of matters of public record is limited to the existence and authenticity of a document; the veracity and validity of the contents remain open to

dispute." Bernardi v. JPMorgan Chase Bank, NA., No. C–11–04543 RMW, 2012 WL 33894, *1 n.1 (N.D. Cal., Jan. 6, 2012).

B. Instacare and Pharmatech's Motion for Judgment on the Pleadings Regarding Allegations of Future Infringement

First, Instacare and Pharmatech argue that they are entitled to judgment on the pleadings because the Complaint fails to allege that any Defendant has a test strip product approved for sale by the FDA or on the market and thus LifeScan's lawsuit is premature. LifeScan argues that it has properly alleged a declaratory judgment action even though the Genstrips have not yet received FDA approval because Defendants' entrance into the market is imminent. In its reply brief, Instacare and Pharmatech argue that the alleged conduct is not sufficiently definite and imminent to satisfy the case or controversy requirement for Article III jurisdiction.

1. Immediacy

LifeScan argues that Defendants will launch the Genstrip Product imminently based on the following facts. On May 24, 2011, Instacare published a Financial Guidance memo on its website stating that it expected to realize revenues of $41.8 million in 2011 and $202.6 million in 2012 from sales of the Genstrip. Compl. ¶ 32. In the Form 10-Q/A signed September 14, 2011, Instacare represented to the S.E.C. that it expected to introduce the Genstrip in the fourth quarter of 2011. Howard Decl. Ex. A at 12. In this filing, InstaCare also told the S.E.C. that it had accepted "pre-orders" for the Shasta Genstrip product but ended the "pre-order initiative" because "the initial interest outstripped the initially available manufacturing capacity" Id. As recently as January 5, 2012, PharmaTech's website stated that it had accepted 1,500,000 pre-orders for the Shasta Genstrip. Howard Decl. Ex. D.

In the Form 10-Q signed November 21, 2011, Instacare represented to the SEC that "all regulatory hurdles [for approval of the Genstrip] have been addressed," described the Genstrip as the "company's current product offering," and stated that it has "continued to gear up" to introduce the product to the market, which "on its first day of commercial availability, will be by far the company's largest selling product." Howard Decl., Ex. B at 13-14. In addition to these

representations, LifeScan alleges that Defendants have engaged in commercial activities in connection with the expected launch of the Genstrip, including entering into agreements to distribute and to manufacture Genstrips, and having Genstrips made and stockpiling Genstrips for distribution within the U.S. Compl. ¶¶ 61, 63, 69, 72.

Instacare and Phamatech, however, argue that the allegation that they are stockpiling Genstrips for distribution is false and any production of Genstrips has been for uses related to gaining FDA approval and therefore are covered by Section 271(e)(1) exception. In support of its argument that the Section 271(e)(1) exception applies to any production of Genstrips that has taken place, Instacare and Pharmatech cite to the declaration of Shasta's Managing Member, Calvin Knickerbocker, that Shasta had vials of the Genstrip manufactured and sealed in vials to comply with the FDA requirement that the devices be tested for shelf life and that the samples were not packaged, labeled, or ready for sale to the consumer. Knickerbocker Decl. ¶ 5, Docket No. 37. Knickerbocker also states that "Shasta completed its clinical testing," id. ¶ 12, and that he "do[es] not anticipate FDA approval in the next 60 days," id. ¶ 14. Instacare and Pharmatech argue that due to the uncertain timeframe of FDA approval there is also no real and immediate threat of any alleged patent infringement.

In determining whether an actual controversy exists, courts consider the nature of the acts and whether they suggest that infringement is sufficiently immediate. Lang, 895 F.2d at 764. Although the date of FDA approval is uncertain, Instacare's statements to the SEC indicate that that date will be imminent. Instacare represented that it believed it would introduce the Genstrips last year and that all hurdles to FDA approval have been overcome.[1] Kinckerbocker's statement

[1] Instacare and Pharmatech do not dispute that the statements made in their SEC filings were true nor do they "in any way wish to distance themselves from the statements made in the SEC filing or other public statements." Defs' Reply 12(c) Mot. Judgment on the Pleadings at 1:15-16. Instead, in their objection to LifeScan's request for judicial notice, Instacare and Pharmatech object generally to its SEC filings, websites, and press releases being used to prove the truth of the statements they contain as hearsay. To the extent that Instacare or Pharmatech argue that the statements contained within the SEC reports are hearsay, they are incorrect. The text of the SEC filings indicate that they were submitted by Instacare's Chief Financial Officer and Principal Accounting Officer, and Instacare does not offer evidence to the contrary. As a party to this action,

that FDA approval is not anticipated in the next 60 days does not indicate the alleged infringement is sufficiently remote to defeat jurisdiction. Cf. Telectronics Pacing Systems, Inc. v. Ventritex, Inc., 982 F.2d 1520, 1527 (Fed. Cir. 1992) (finding that the case lacked sufficient immediacy where defendant's device had only recently begun clinical trials, and was years away from potential FDA approval).

A substantial portion of Instacare and Pharmatech's motion argues that all their conduct alleged in LifeScan's complaint falls within the § 271(e)(1) safe harbor. To the extent, Instacare and Pharmatech argue that exempted acts cannot be considered as indicia that an actual controversy exists, that argument fails. Even if some of Instacare and Pharmatech's acts that form the basis of the declaratory judgment action are protected from liability for infringement under § 271(e)(1), the protected status of Instacare and Pharmatech's activities leading to its submissions to the FDA does not by itself prevent the district court from considering LifeScan's request for declaratory relief because such relief is directed to the time after FDA approval, when § 271(e)(1) no longer provides shelter against infringement liability." See Glaxo v. Novopharm, Ltd, 110 F.3d 1562, 1571 (Fed. Cir. 1997). In Glaxo, the Federal Circuit held that "[allegations sufficient to establish a case or controversy] may include, . . . imminent FDA approval and actual threats of future infringement. Therefore, the district court properly exercised its discretion to hear [plaintiff]'s declaratory judgment action, even though the action was premised in part on actions protected under § 271(e)(1)." Id.

Further, the acts of making representations to the S.E.C. and entering into agreements to distribute and to manufacture are not acts covered by the Section 271(e)(1) exemption because, they are not acts of "making, selling, or offering to sell" the infringing product under section 271(a). As in Glaxo, where preparing to import the product was considered in determining jurisdiction, preparing to make or sell the product may also be properly consider as meaningful preparation, and these acts, in no way implicate the section 271(e)(1) exemption.

Instacare's admissions are not hearsay. See Fed. R. Evid. 801(d)(2)(C); Florida Conference Ass'n of Seventh-Day Adventists v. Kyriakides, 151 F. Supp. 2d 1223, 1225 (C.D. Cal. 2001).

Shasta's completion of its clinical trials; Instacare's representations to the S.E.C. that it expected to being selling the Genstrips last year, that all remaining hurdles to FDA approval have been addressed, that there was a high demand for pre-orders, and that on the Genstrips' first day of commercial availability it will be Instacare's biggest seller; the existence of agreements to distribute and to manufacture; and allegations that Defendants have begun stockpiling Genstrips for distribution establish the existence of the immediacy required by Lang.

2. Reality

The "reality" test is also satisfied in this case. On June 24, 2011, LifeScan allege they sent a letter to InstaCare with copies to Shasta and Conductive stating that "LifeScan believes that it is likely that the current and future activities of Shasta in manufacturing, selling and offering for sale the Shasta Genstrip constitute infringement of certain United States patents owned by LifeScan relating to test strips and methods of their use and manufacture including U.S. Patent Nos. 5,708,247; 5,951,836; 6,241,862; 7,112,265; 7,250,105 and 7,462,265." See Compl. ¶¶ 34-36. By that letter, LifeScan sought manufacturing information and samples from Defendants that would allow it to make a complete analysis to determine whether or not Genstrips infringed LifeScan's patents. Id. On July 1, 2011, Instacare and Pharmatech responded that they did not possess that information. Compl. ¶ 39. On July 15, 2011, LifeScan requested samples again. On July 21, 2011, InstaCare and PharmaTech responded to the July 15th letter by indicating that their "position remained unchanged." Id. ¶ 50. On September 1, 2011, LifeScan wrote to the Defendants and repeated the request for manufacturing information and samples. Id. In the September 1st letters, LifeScan informed the Defendants that if they continued to remain silent or refuse to produce the requested information and samples, the "only reasonable inference" is that the Defendants recognize that "that its activities constitute infringement of LifeScan's patents and that it is attempting to hide them." Id. ¶ 52.

LifeScan's letters to Defendants stating that it believed the current and future making and selling of Genstrips infringed LifeScan's patents and that LifeScan would interpret Defendants' refusal to provide information about the manufacturing process as efforts to hide infringement are

acts sufficient to create a reasonable apprehension that a suit will be forthcoming. Defendants do not appear to have changed the course of their action in the face of these acts. Instacare and Pharmatech have made no argument with respect to the sufficiency of the "reality" element. The evidence suggests a refusal of Instacare and Pharmatech to change course in spite of threats of litigation from Amgen and predictions of litigation from outside parties.

Given that the test for the existence of an actual controversy is satisfied, the court is warranted in exercising jurisdiction over this declaratory judgment action.

C. Instacare and Pharmatech's Motion To Stay

Instacare and Pharmatech argue that the court should stay this litigation because: (1) there is no product on the market so LifeScan cannot be harmed by Defendants' activities; (2) the court's rulings will be purely advisory if the FDA could never approve the Genstrips or the Genstrips could materially change before receiving approval; (3) any uncertainty about the form of the Genstrips that will be approved will complicate and hamper the litigation; and (4) allowing a lawsuit to proceed because activities protected by § 271(e)(1) are indicative of future infringing-acts is inconsistent with the goal of § 271 and renders the protections of § 271(e)(1) illusory.

It is unclear whether Instacare and Pharmatech request that the court exercise its discretion to decline jurisdiction or that the court stay the proceeding under the court's broad discretion to stay cases when it is "efficient for its own docket and the fairest course for the parties." Levya v. Certified Grocers of California, Ltd., 593 F. 2d 857, 863 (9th Cir. 1979). The court finds that a stay is not appropriate at this time for either reason.

With regard to Instacare and Pharmatech's first argument, although the product is not currently on the market, as discussed above, there are sufficient indicia that its approval and subsequent infringing activities are real and imminent. Additionally, staying this action until FDA approval will hamper LifeScan's ability to seek an order enjoining Defendants' alleged infringement after FDA approval. Instacare and Pharmatech's second and third argument hinge on the potential that the Genstrips will be altered before approval. Instacare and Pharmatech, however, have not supplied any evidence that alteration is likely. Although Shasta has been required to

modify the Genstrips twice before, see Knickerbocker Decl. ¶¶ 8, 11, Instacare's representations that it expected to enter the market in 2011, indicating FDA approval is in its final states, offset the likelihood of a further alteration to the Genstrips.

With regard to Instacare and Pharmatech's final argument, some of the acts showing an actual controversy are clearly within the § 271(e)(1) safe harbor, such as Shasta's having completed clinical trials. As discussed above, many of the acts are clearly outside of the safe harbor because they would not otherwise be acts of infringement. Where the only current acts giving rise to jurisdiction fall within the safe harbor or are otherwise non-infringing, courts have declined to exercise their jurisdiction. See Intermedics, Inc. v. Ventritex, Inc., 775 F. Supp. 1269, 1290 (N.D. Cal. 1991) (dismissing declaratory relief claims, where the court held on summary judgment that all current acts were protected by the safe harbor provision, because exercising jurisdiction would undermine one of Congress' purposes in enacting the § 271(e)(1) exemption); Amgen, Inc. v. Hoechst Marion Roussel, Inc., 3 F. Supp. 2d 104, 109-113 (D. Mass 1998) (declining to exercise jurisdiction, where the court held on summary judgment that all current acts were protected by the safe harbor provision, because subjecting the Defendants to an infringement litigation at present may run afoul of the Congressional policy underlying the section 271(e)(1) exemption).

Here, however, LifeScan also alleges a current act of infringement outside of the safe harbor provision. Specifically, LifeScan, alleges that Shasta, Instacare, and Pharmatech "have actively induced infringement by having Genstrips made for distribution within the United States," and Defendants are "stockpiling Genstrips in the United States for distribution upon regulatory approval." Compl. ¶¶ 61, 63, 69, 72. Instacare and Pharmatech argue the only manufacture of Genstrips to date has been for uses related to FDA approval.

The court cannot conclude, as matter of law, that because Defendants are in the process of submitting information to the FDA, that any production of the Genstrips must be solely for uses that reasonably relate to the submission of that information. See Amgen, 456 F. Supp. 2d. at 273; Amylin Pharma. v. Regents of the Univ. of Minnesota, No. 96cv2061 JM(POR), 1998 WL 119511, *3 (S.D. Cal. Jan. 15, 1998) (denying a motion to dismiss based on the safe harbor provision

because a factual dispute existed as to the applicability of the provision that should not be resolved on a motion to dismiss). The courts in Intermedics and Hoechst made their rulings on a motion for summary judgment, holding, consistent with what discovery revealed, that all the defendant's current acts were protected by the safe harbor provision. This court has made no such ruling and faced with a motion for judgment on the pleadings, "the court must presume—based on [plaintiff]'s allegations—that [defendants] are operating outside the safe harbor exemption." See Amgen, 456 F. Supp. 2d at 267 (denying a motion to dismiss and exercising jurisdiction over plaintiff's declaratory judgment claim). Accordingly, the court will not decline jurisdiction over this case at this time.

Thus, Instacare and Pharmatech's motion for judgment on the pleadings as to LifeScan's allegations that Instacare and Pharmatech will infringe the patents-in-suit is DENIED.

D. Instacare and Pharmatech's Motion for Judgment on the Pleadings Regarding Allegations of Current Infringement

Instacare and Pharmatech also argue that the Complaint fails to allege any act of current infringement outside of the safe harbor exemption, and therefore LifeScan does not state a claim for current infringement.

As discussed above, LifeScan alleges that Shasta, Instacare, and Pharmatech "have actively induced infringement by having Genstrips made for distribution within the United States," and Defendants are "stockpiling Genstrips in the United States for distribution upon regulatory approval." Compl. ¶¶ 61, 63, 69, 72. Thus, LifeScan has alleged that Genstrips are being made—an act of infringement under 35 U.S.C. 271 (a)—and that Shasta, Instacare, and Pharmatech have induced that act. See 35 U.S.C. 271(b).

Instacare and Pharmatech argue that (1) this allegation does not apply to them because they are not manufacturers; (2) the only manufacturing of Genstrips that has taken place is protected by the safe harbor; (3) it does not make business sense to stockpile a product that might change before it is approved by the FDA; and (4) the Complaint does not cite the source of this information.

Instacare and Pharmatech's first three arguments merely dispute the facts asserted in the Complaint. On a motion for judgment on the pleadings, however, "all material allegations in the complaint are accepted as true and construed in the light most favorable to the non-moving party." Turner, 362 F.3d at 1225. The motion therefore cannot be granted on these grounds. With regard to Instacare and Pharmatech's fourth argument, failure to plead facts sufficient to state a claim is basis for granting a motion for judgment on the pleadings. Here, however, Instacare and Pharmatech have not identified any element of an infringement claim that is insufficiently pleaded.

Thus, Instacare and Pharmatech's motion for judgment on the pleadings as to LifeScan's allegations that Instacare and Pharmatech is currently infringing the patents-in-suit is DENIED.

E. Shasta and Conductive's Motion To Stay

Shasta and Conductive move for a stay pending the FDA's approval of the Genstrips. In support of its motion, Shasta and Conductive make many of the arguments addressed above — (1) the FDA may never approve the Genstrip; (2) it is unclear which iteration of the test strip will be approved for sale to consumers; and (3) LifeScan will not be prejudiced because there are no sales of the Genstrips.

The competing interests that a district court must weigh in deciding whether to grant a stay include: (1) "possible damage which may result from the granting of a stay, (2) the hardship or inequity which a party may suffer in being required to go forward, and (3) the orderly course of justice measured in terms of the simplifying or complicating of issues, proof, and questions of law which could be expected to result from a stay." Negotiated Data Solutions, LLC v. Dell Inc., No. CV-03-05755 JSW, 2008 WL 4279556, at *1 (N.D. Cal. Sept. 16, 2008). "A stay may be the most efficient and fairest course when there are 'independent proceedings which bear upon the case.'" Id. (citing Levya, 593 F.2d at 863).

For the same reasons Instacare and Pharmatech's motion to stay was denied, Shasta and Conductive's motion is also denied. There are sufficient indicia that the Genstrips' approval and Defendants' subsequent infringing activities are real and imminent, and staying this action until FDA approval will hamper LifeScan's ability to seek an order enjoining Defendants' alleged

infringement. Thus, a stay could prejudice LifeScan. The only hardship that Shasta and Conductive have identified if the case goes forward is waste of resources if the FDA does not approve the current iteration of the Genstrips. Shasta and Conductive, however, have not supplied evidence demonstrating that alteration is likely, and Instacare's representations regarding the expected date of FDA approval offsets the probability of a substantial alteration. Avoiding this waste of resources is also the only benefit gained by waiting for the FDA process to conclude that Shasta and Conductive have identified. The evidence supporting this benefit is lacking for the same reasons.

Thus, these considerations do not warrant a stay at this time. Shasta and Conductive's motion to stay therefore is DENIED.

IV. CONCLUSION

For the reasons above, Instacare and Pharmatech's motion for judgment on the pleadings or, in the alternative, to stay and Shasta and Conductive's motion to stay are DENIED.

In light of this order and its effect on the need for discovery, the court CONTINUES the case management conference scheduled for July 20, 2012 to August 24, 2012. The parties shall submit an updated case management statement included a proposed schedule no later than August 17, 2012.

Dated: July 19, 2012

EDWARD J. DAVILA
United States District Judge